

§ 522.1850

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987]

§ 522.1850 Polysulfated glycosaminoglycan.

(a) *Specifications.* Each 1-milliliter ampule of sterile aqueous solution contains 250 milligrams of polysulfated glycosaminoglycan; each 5-milliliter ampule or vial contains 500 milligrams.

(b) *Sponsor.* See No. 010797 in § 510.600(c) of this chapter.

(c) *Conditions of use—horses.* (1) *Indications for use.* Polysulfated glycosaminoglycan is for the treatment of noninfectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.—

(2) *Amount—(i) Intra-articular use (carpal):* 250 milligrams once a week for 5 weeks. The joint area must be shaved, cleaned, and sterilized as in a surgical procedure prior to injection. If the joint reacts with excessive inflammation, after intra-articular treatment, cease therapy.

(ii) *Intramuscular use (carpal and hock):* 500 milligrams every 4 days for 28 days. Injection site must be thoroughly cleansed prior to injection.

(3) *Limitations.* Not for use in horses intended for food. Safe use in breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use—dogs—(1) Indications for use.* For control of signs associated with noninfectious degenerative and/or traumatic arthritis of canine synovial joints.

(2) *Dosage.* 2 milligrams per pound of body weight by intramuscular injection.

(3) *Limitations.* Administer intramuscularly twice weekly for up to 4 weeks (maximum of 8 injections). Do not exceed recommended dose or regimen. Do not mix with other drugs or solvents. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 53053, Dec. 27, 1989, as amended at 61 FR 54333, Oct. 18, 1996; 62 FR 45158, Aug. 26, 1997]

21 CFR Ch. I (4–1–05 Edition)

§ 522.1862 Sterile pralidoxime chloride.

(a) *Chemical name.* 2-Formyl-1-methylpyridinium chloride oxime.

(b) *Specifications.* Sterile pralidoxime chloride is packaged in vials. Each vial contains 1 gram of sterile pralidoxime chloride powder and includes directions for mixing this gram with 20 cubic centimeters of sterile water for injection prior to use.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is used in horses, dogs, and cats as an antidote in the treatment of poisoning due to those pesticides and chemicals of the organophosphate class which have anticholinesterase activity in horses, dogs, and cats.

(2) It is administered as soon as possible after exposure to the poison. Before administration of the sterile pralidoxime chloride, atropine is administered intravenously at a dosage rate of 0.05 milligram per pound of body weight, followed by administration of an additional 0.15 milligram of atropine per pound of body weight administered intramuscularly. Then the appropriate dosage of sterile pralidoxime chloride is administered slowly intravenously. The dosage rate for sterile pralidoxime chloride when administered to horses is 2 grams per horse. When administered to dogs and cats, it is 25 milligrams per pound of body weight. For small dogs and cats, sterile pralidoxime chloride may be administered either intraperitoneally or intramuscularly. A mild degree of atropinization should be maintained for at least 48 hours. Following severe poisoning, a second dose of sterile pralidoxime chloride may be given after 1 hour if muscle weakness has not been relieved.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 49 FR 32061, Aug. 10, 1984]

§ 522.1870 Praziquantel injectable solution.

(a) *Specification.* Each milliliter contains 56.8 milligrams of praziquantel.

(b) *Sponsors.* See 000859 and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. For dogs 5 pounds and under, 0.3 milliliter (17.0 milligrams); for 6 to 10 pounds, 0.5 milliliter (28.4 milligrams); for 11 to 25 pounds, 1.0 milliliter (56.8 milligrams); if over 25 Pounds, 0.2 milliliter (11.4 milligrams) per 5 pounds body weight to a maximum of 3 milliliters (170.4 milligrams).

(ii) *Indications for use*. For removal of canine cestodes *Dipylidium caninum*, *Taenia pisiformis*, and *Echinococcus granulosus*, and removal and control of canine cestode *Echinococcus multilocularis*.

(iii) *Limitations*. For subcutaneous or intramuscular use; not intended for use in puppies less than 4 weeks of age; Federal law restricts the drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. For cats under 5 pounds, 0.2 milliliter (11.4 milligrams); 5 to 10 pounds, 0.4 milliliter (22.7 milligrams); 11 pounds and over, 0.6 milliliter (34.1 milligrams) maximum.

(ii) *Indications for use*. For removal of feline cestodes *Dipylidium caninum* and *Taenia taeniaeformis*.

(iii) *Limitations*. For subcutaneous or intramuscular injection only. Not intended for use in kittens less than 6 weeks of age. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 10464, Feb. 3, 1981, as amended at 47 FR 6617, Feb. 16, 1982; 58 FR 42853, Aug. 12, 1993; 67 FR 79853, Dec. 31, 2002]

§ 522.1881 Sterile prednisolone acetate aqueous suspension.

(a) *Specifications*. Each milliliter of sterile aqueous suspension contains 25 milligrams of prednisolone acetate.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *NAS/NRC status*. The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter but may require bioequivalency and safety information.

(d) *Conditions of use*. (1) The drug is indicated in the treatment of dogs, cats, and horses for conditions requiring an anti-inflammatory agent. The drug is indicated for the treatment of acute musculoskeletal inflammations

such as bursitis, carpalitis, and spondylitis. The drug is indicated as supportive therapy in nonspecific dermatosis such as summer eczema and atopy. The drug may be used as supportive therapy pre- and post-operatively and for various stress conditions when corticosteroids are required while the animal is being treated for a specific condition.

(2) The drug is administered to horses intra-articularly at a dosage level of 50 to 100 milligrams. The dose may be repeated when necessary. If no response is noted after 3 or 4 days, the possibility must be considered that the condition is unresponsive to prednisolone therapy. The drug is administered to dogs and cats intramuscularly at a dosage level of 10 to 50 milligrams. The dosage may be repeated when necessary. If the condition is of a chronic nature, an oral corticosteroid may be given as a maintenance dosage. The drug may be given intra-articularly to dogs and cats at a dosage level of 5 to 25 milligrams. The dose may be repeated when necessary after 7 days for two or three doses.

(3) The labeling shall comply with the requirements of § 510.410 of this chapter for corticosteroids.

(4) Not for use in horses intended for food.

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[52 FR 23032, June 17, 1987]

§ 522.1883 Prednisolone sodium phosphate.

(a) *Specifications*. Each milliliter of solution contains 20 milligrams (mg) prednisolone sodium phosphate (equivalent to 14.88 mg of prednisolone).

(b) *Sponsor*. See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Administer intravenously in a dosage of 2 1/2 to 5 mg per pound of body weight, initially for shock and shock-like states, followed by equal maintenance doses at 1-, 3-, 6-, or 10-hour intervals as determined by the condition of the animal.

(2) *Indications for use*. Administer when a rapid adrenal glucocorticoid and/or anti-inflammatory effect is necessary.